IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ROBIN KRAMER,	*	
Plaintiff,	*	
v.	*	Civil Action No. GLR-20-3747
ETHICON, INC., et al.,	*	
Defendants.	*	

***

MEMORANDUM OPINION

THIS MATTER is before the Court on Defendants Ethicon, Inc., Ethicon, LLC, and Johnson & Johnson's (collectively, "Defendants" or "Ethicon") Motion for Judgment on the Pleadings (ECF No. 18). The Motion is ripe for disposition, and no hearing is necessary. See Local Rule 105.6 (D.Md. 2021). For the reasons outlined below, the Court will grant in part and deny in part Ethicon's Motion.

I. BACKGROUND[1]

A. Kramer's Injuries

Plaintiff Robin Kramer suffered from pelvic organ prolapse and sought surgical treatment. (Compl. ¶ 85, ECF No. 1). On May 5, 2011, Dr. Leslie Rickey performed surgery at University of Maryland Medical Center to implant Kramer with a "Mesh Prolene Soft Polypropylene 10x10" device designed and manufactured by Ethicon. (Id.). After the

[1] Unless otherwise noted, the Court takes the following facts from the Complaint and accepts them as true. See Erickson v. Pardus, 551 U.S. 89, 94 (2007).

procedure, Kramer began experiencing painful complications including "erosion of the mesh through her tissue, dyspareunia, and post coital bleeding." (Id. ¶ 86).

Kramer underwent three additional surgeries to excise and remove the implanted mesh product. (Id. ¶ 92). On April 7, 2016, Dr. Andrew Sokol tried to remove the mesh at Georgetown University Hospital in Washington, DC. (Id. ¶ 87). As the mesh was designed "to incorporate itself and embed itself within tissue," Dr. Sokol could not remove it all during the surgery. (Id. ¶ 88). On June 13, 2017, Dr. Sokol operated on Kramer a second time "to excise eroded mesh and a permanent mesh-related suture." (Id. ¶ 89). Unfortunately, Dr. Sokol again could not remove all the mesh and the mesh continued to erode.[2] (Id. ¶ 90). Finally, on August 15, 2019, Dr. Sokol performed a third surgery to remedy the continued erosion of the mesh and remove another mesh suture at Medstar Washington Hospital Center Urogynocology in Chevy Chase, Maryland. (Id.).

Even after the three removal procedures, Kramer "still lives with partially eroded mesh inside her body." (Id. ¶ 91). She continues to experience pain, dyspareunia, and bleeding after sex and alleges that she has experienced mental and physical pain and suffering, permanent injury, financial loss, and other damages. (Id. ¶¶ 91, 93).

B. Surgical Mesh Generally

Surgical mesh products have been used to repair abdominal hernias since the 1950s. (Id. ¶ 11). In the 1970s, gynecologists began using mesh products designed for treating

[2] Although Kramer does not state so directly, the Court infers that Dr. Sokol could not remove all the mesh during the second excision procedure because Kramer contends that the mesh continued to degrade in her system.

hernias to repair prolapsed organs. (Id.). By the 1990s, gynecologists used surgical mesh in the treatment of pelvic organ prolapse, the condition Kramer suffers from, and stress urinary incontinence. (Id. ¶¶ 11, 85). Manufacturers, including Ethicon, modified the mesh initially used in hernia repair to specifically treat pelvic organ prolapse and stress urinary incontinence. (Id. ¶ 11).

Kramer alleges that Ethicon was "aware that, after the development of hernia-similar mesh for treatment of [pelvic organ prolapse and stress urinary incontinence], surgeons continued to utilize original hernia mesh for treatment of those same conditions." (Id. ¶ 12). Kramer states that, to the extent she was implanted with hernia mesh instead of "an exact or near-exact duplicate 10x10 transvaginal-marketed mesh product," her factual allegations "apply in tandem." (Id.).

In any event, mesh products used to treat pelvic organ prolapse and stress urinary incontinence are designed to remediate weakening of or damage to the walls of the vagina. (Id. ¶ 13). The mesh products, which Kramer describes in general terms, were "promoted to physicians and patients" as minimally invasive with minimum tissue reactions or trauma. (Id.). The products, however, contain polypropylene mesh, which is "biologically incompatible with human tissue." (Id. ¶ 14). As such, they "promote[] an immune response in a large subset of the population." (Id.). The immune response, in turn, promotes the degradation of the polypropylene mesh, as well as some pelvic tissue, and can contribute to the "formation of severe adverse reactions to the mesh." (Id.).

On October 20, 2008, the Food and Drug Administration issued a Public Health Notification outlining over 1,000 complaints it had received over a three-year period

regarding mesh products. (Id. ¶ 25). Kramer asserts that the FDA's Manufacturer and User Facility Device Experience ("MAUDE") database indicates that Ethicon's pelvic mesh products were the subject of the 2008 notification. (Id.).

On July 13, 2011, the FDA issued a warning about complications associated with mesh products. (Id. ¶ 26). The warning stated that "serious complications" related to the use of surgical mesh for treatment of pelvic organ prolapse are "not rare." (Id.). In December 2011, the American College of Obstetricians and Gynecologists and the American Urogynecologic Society "also identified physical and mechanical changes to the mesh." (Id. ¶¶ 31–32).

C. Procedural History

On December 28, 2020, Kramer filed suit against Ethicon. (ECF No. 1). The Complaint alleges claims against Defendants for: negligence (Count I); strict liability – manufacturing defect (Count II); strict liability – failure to warn (Count III); strict liability – defective product (Count IV); strict liability – design defect (Count V); common law fraud (Count VI); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent misrepresentation (Count IX); negligent infliction of emotional distress (Count X); breach of express warranty (Count XI); breach of implied warranty (Count XII); violation of consumer protection laws (Count XIII); and gross negligence (Count XIV). (Compl. ¶¶ 94–227). Kramer seeks compensatory damages, economic damages, punitive damages, treble damages, and attorneys' fees and costs. (Id. ¶ 229).

On March 29, 2021, Ethicon filed a Motion for Judgment on the Pleadings moving to dismiss Kramer's claims in their entirety. (ECF No. 18). On April 20, 2021, Kramer

filed her Opposition, contesting some of Ethicon's arguments but also agreeing to voluntarily withdraw Counts IV, VIII, X, XI, XII, and XIII. (ECF No. 22).[3] Ethicon filed its Reply on May 5, 2021. (ECF No. 25). On August 24, 2021, Ethicon filed a Notice of Supplemental Authority in support of its Motion. (ECF No. 27).

II. DISCUSSION

A. Standard of Review

Under the Federal Rules of Civil Procedure, "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." Fed.R.Civ.P. 12(c). The Court applies the same standard to Rule 12(c) motions for judgment on the pleadings and 12(b)(6) motions to dismiss for failure to state a claim. Massey v. Ojaniit, 759 F.3d 343, 347 (4th Cir. 2014). The Court tests "the sufficiency of a complaint" but will not "resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." King v. Rubenstein, 825 F.3d 206, 214 (4th Cir. 2016) (quoting Edwards v. City of Goldsboro, 178 F.3d 231, 243 (4th Cir. 1999)). As the Court addresses sufficiency, it bears in mind the requirements of Federal Rule of Civil Procedure 8, Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007), and Ashcroft v. Iqbal, 556 U.S. 662 (2009). A complaint must include "a short and plain statement of the claim showing that the pleader is entitled to relief," Fed.R.Civ.P. 8(a)(2), and state "a plausible claim for relief," Iqbal, 556 U.S. at 678–79. A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is

[3] The Court will accordingly grant Defendants' Motion as to Counts IV, VIII, X, XI, XII, and XIII.

liable for the misconduct alleged." Id. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Id. Although the plaintiff is not required to forecast evidence to prove the elements of the claim, the complaint must allege sufficient facts to establish each element. Goss v. Bank of Am., N.A., 917 F.Supp.2d 445, 449 (D.Md. 2013) (quoting Walters v. McMahen, 684 F.3d 435, 439 (4th Cir. 2012)), aff'd, 546 F.App'x 165 (4th Cir. 2013).

In considering a 12(c) motion, "all well-pled facts are assumed to be true and all reasonable inferences are drawn in favor of the non-moving party." Language Doctors, Inc. v. MCM 8201 Corporate, LLC, No. PWG-20-1755, 2021 WL 718940, at *3 (D.Md. Feb. 24, 2021); Belmora LLC v. Bayer Consumer Care AG, 819 F.3d 697, 702 (4th Cir. 2016). "Ultimately, a defendant may not prevail on a motion for judgment on the pleadings if there are pleadings that, if proved, would permit recovery for the plaintiff." Somerville v. West Town Bank & Trust, No. PJM-19-490, 2020 WL 8256358, at *1 (D.Md. Dec. 4, 2020). "Moreover, unlike a Rule 12(b)(6) motion, a Rule 12(c) motion requires the court to consider and decide the merits of the case, on the assumption that the pleadings demonstrate that there are no meaningful disputes as to the facts such that the complaint's claims are ripe to be resolved at this very early stage of the litigation." Id. A motion for judgment on the pleadings "should not be granted unless it appears to a certainty that the non-moving party cannot prove any set of facts in support of its claim that would entitle it to relief." United States v. Castillo, No. PWG-19-3459, 2021 WL 825974, at *3 (D.Md. Mar. 4, 2021) (quoting Shooting Point, LLC v. Cumming, 238 F.Supp.2d 729, 735 (E.D.Va. 2002)).

B. Analysis

1. Design Defect

Kramer asserts claims premised in whole or in part on an alleged design defect. Kramer's design defect claims form part of her negligence claims (Counts I & XIV) and all of her strict liability – design defect claim (Count V). As Kramer adequately alleges her design defect claims, the Court will deny Defendants' Motion as to Count V in its entirety and Counts I and XIV to the extent those counts arise from an alleged design defect.

In Maryland, negligent design defect and strict liability design defect are substantively similar claims for purposes of 12(b)(6), and by extension, 12(c). "A products liability design defect claim 'focuses upon the specifications for the construction of the product and the risks and benefits associated with that design.'" Morris v. Biomet, Inc., 491 F.Supp.3d 87, 103 (D.Md. 2020) (quoting Shreve v. Sears, Roebuck & Co., 166 F.Supp.2d 378, 411 (D.Md. 2001)). The negligence theory, on the other hand, "focuses on the conduct of the defendant." Id. (quoting Parker v. Allentown, Inc., 891 F.Supp.2d 773, 780 (D.Md. 2012)). Both theories, however, require a showing of the same three elements, "defect, attribution of defect to the seller, and a causal relationship between the defect and the injury." Id. Accordingly, "the elements of proof are the same whether the claim [is] characterized as one for strict liability or negligence." McCoy v. Biomet Orthopedics, Inc., No. ELH-12-1436, 2021 WL 252556, at *22 (D.Md. Jan. 25, 2021) (quoting Heckman v. Ryder Truck Rental, Inc., 962 F.Supp.2d 792, 802 (D.Md. 2013)). As the claims either rise or fall together, the Court will address them simultaneously.

Ethicon raises two primary arguments regarding Kramer's design defect claim. First, Ethicon argues that Kramer only includes "vague and conclusory allegations" in her Complaint and she therefore fails to "identify flaws in any of the products' design." (Mem. Supp. Defs.' Mot. J. Pleadings ["Defs.' Mot."] at 7, ECF No. 18-1). Second, Ethicon argues that even if Kramer alleges a defect, she does not plead any facts "that would plausibly link her injuries to the alleged defects." (Id.). Kramer responds that she alleges several defects in her Complaint and that she also describes the causal mechanism of her injuries. (Pl.'s Mem. Law Supp. Opp'n Defs.' Mot. J. Pleadings ["Pl.'s Opp'n"] at 9, ECF No. 22-1). The Court agrees with Kramer.

Here, Kramer adequately alleges a number of potential defects in the design of the mesh product. Kramer offers the following defects, which the Court has simplified and pared down to account for redundancy:

- The use of polypropylene material causes immune responses that lead to negative immune responses and injuries;
- The insertion of the mesh products through areas with high amounts of bacteria, yeast, and fungus that then adheres to the mesh material, causing immune responses and injuries;
- Biomechanical issues with the mesh that cause tissue to degrade;
- The propensity for the products "to contract, retract, and/or shrink inside the body;
- The propensity for the products to become deformed;

- The "inelasticity" of the products causing them to become mated to areas in the pelvis, causing pain; and
- The propensity of the products to degrade and cause chronic inflammatory reactions.

(Compl. ¶ 20). Ethicon's argument that Kramer fails to identify a defect is therefore unconvincing.

Next, Kramer alleges facts that link her injuries to the alleged defects. Ethicon argues that Kramer offers only general language tying her injuries to a design defect and that she fails to distinguish her injuries from those that might be consistent with any pelvic organ prolapse surgery. (Defs.' Mot. at 7–8). The Court is again unconvinced. In her Complaint, Kramer alleges that the underwent surgery to treat her pelvic organ prolapse in 2011, during which time Dr. Leslie Rickey implanted her with "the Ethicon Mesh Prolene Soft Polypropylene 10x10" product. (Compl. ¶ 85). She contends that after the surgery, she suffered from "painful and serious complications, including but not limited to erosion of the mesh through her tissue, dyspareunia, and post coital bleeding." (Id. ¶ 86). Kramer then alleges that she underwent three separate surgeries performed by Dr. Andrew Sokol "to excise and remove the mesh." (Id. ¶¶ 87–91). She alleges that the mesh was "designed to incorporate itself and embed itself within tissue," presumably making it more difficult to remove from the body. (Id. ¶ 88). She moreover describes the propensity for the mesh to erode in her system and explains that despite her three surgeries to remove the mesh, she "still lives with partially eroded mesh inside her body." (Id. ¶¶ 20, 91). These factual allegations are sufficient to connect the alleged design defects to her injuries.

Ethicon cites Dolan v. Boston Sci. Corp., No. 20-CV-1827 (NEB/LIB), 2021 WL 698777 (D.Minn. Feb. 23, 2021), in support of its argument that Kramer fails to plead sufficient facts to show either a defect or causation. (Defs.' Mot. at 8). The case is inapposite. In Dolan, the District Court for Minnesota dismissed the plaintiff's design defect claim where the plaintiff "offer[ed] only conclusory allegations to support proximate causation" isolated in two paragraphs in her complaint described as "legal conclusions devoid of any factual enhancement." 2021 WL 698777, at *2. Here, Kramer explains that she underwent three remedial surgeries to "excise eroded mesh" which was "designed to incorporate itself and embed itself within tissue." (Compl. ¶¶ 88–89). Kramer's allegations are more detailed than the "[t]hreadbare recitals" in Dolan and the Court finds that she states a claim for design defect.

Accordingly, the Court will deny Ethicon's Motion as to Count V in its entirety and Counts I and XIV to the extent they allege a design defect.

2. Failure to Warn

Kramer asserts a claim for failure to warn as part of her negligence claims (Counts I and XIV) and her strict liability – failure to warn claim (Count III). (See, e.g., Compl. ¶¶ 36, 107–14). Kramer sufficiently alleges the claim for Rule 12(c) purposes and the Court will deny Ethicon's Motion as to Count III in its entirety and Counts I and XIV to the extent they allege a defect for failure to warn.

A manufacturer may be liable for failure to warn if it places a product on the market with inadequate instructions and warnings. Stanley v. Central Garden & Pet Corp., 891 F.Supp.2d 757, 763 (D.Md. 2012). The warnings are adequate if they explain the risk the

plaintiff alleges caused her injury. Morris, 491 F.Supp.3d at 104 (quoting Lee v. Baxter Healthcare Corp., 721 F.Supp. 89, 95 (D.Md. 1989)). The duty to warn requires a "reasonable warning, not the best possible one." Stanley, 891 F.Supp.2d at 763 (quoting Nolan v. Dillon, 276 A.2d 36, 40 (Md. 1971)). Accordingly, a manufacturer does not need to "warn of every mishap or source of injury that the mind can imagine flowing from the product." Id. (quoting Liesener v. Weslo, Inc., 775 F.Supp. 857, 861 (D.Md. 1991)). To determine if a warning is adequate, the Court "ask[s] if the benefits of a more detailed warning outweigh the costs of requiring the change." Id. A negligence claim based on a failure to warn is "nearly identical" to a strict liability claim. Id. at 764.

"Maryland courts apply the learned intermediary doctrine in failure to warn cases involving medical devices." Morris, 491 F.Supp.3d at 104. Under the learned intermediary doctrine, the manufacturer of a medical device does not have a duty to warn the patient of the risks associated with the device used under a doctor's supervision. Id. (quoting Miller v. Brystol-Myers Squibb Co., 121 F.Supp.2d 831, 838 (D.Md. 2000)). Instead, the manufacturer has a duty to warn the patient's doctor of the risks associated with the product's use. Id.

Ethicon argues that the learned intermediary doctrine applies to this matter and that Ethicon's duty to warn ran only to Kramer's prescribing surgeon, not Kramer herself. (Defs.' Mot. at 5). It argues further that Kramer does not state a claim because the Complaint discusses pelvic mesh products generally and does not specifically reference the materials that accompanied the Prolene Soft device or indicate why the warnings were deficient. (Id.). Finally, Ethicon argues that Kramer does not plead sufficient facts

regarding proximate causation. (Id. at 6). Kramer responds that Ethicon's learned intermediary argument is "meritless and premature," she adequately pled that Ethicon did not warn physicians of the defects in the mesh products, and she identified how the written materials that accompanied the Prolene Soft were deficient. (Pl.'s Opp'n at 3–9). The Court agrees with Kramer.

First, Ethicon's argument that the learned intermediary doctrine applies in this case does not on its own support the grant of judgment on its behalf. Here, it does appear that the learned intermediary doctrine applies. See Morris, 491 F.Supp.3d at 104 (indicating that the learned intermediary doctrine applies in cases regarding medical devices). Ethicon does not, however, explain why the applicability of the learned intermediary doctrine would warrant judgment at this stage. Indeed, turning to the Complaint, Kramer alleges that Ethicon failed to warn both her and her health care providers of the risks associated with the mesh products. (Compl. ¶¶ 108–11). Accordingly, the Court cannot identify, and Ethicon does not provide, a reason why the application of the learned intermediary doctrine in this case alone warrants judgment on Ethicon's behalf. See Merino v. Ethicon, Inc., 536 F.Supp.3d 1271, 1284–85 (S.D.Fla. 2021) (rejecting Ethicon's argument that application of learned intermediary doctrine warranted dismissal under 12(b)(6) where plaintiff alleged that Ethicon failed to sufficiently warn her physician of a mesh product's risks).

Regardless, the Court will not grant judgment on the failure to warn claim at this early stage where the facts surrounding the adequacy of the warnings given to Dr. Rickey are still undeveloped. As Kramer explains, the parties have yet to depose Dr. Rickey to inquire about the nature of the warnings she received, whether she was independently

aware of the risks when she prescribed the mesh product, or whether Ethicon's warnings affected her treatment decisions. Without more, the Court is unable to make the necessary factual determinations regarding whether Ethicon adequately informed Dr. Rickey of the risks and whether such a warning might have moved Dr. Rickey to alter Kramer's care. And, given the fact that additional information pertinent to this claim is known by Dr. Rickey and not Kramer, the Court finds that Kramer's at times general allegations regarding failure to warn are sufficient at this stage. As such, the Court will deny judgment on Kramer's failure to warn claim. See Runner v. C.R. Bard, 108 F.Supp.3d 261, 272 (E.D.Pa. 2015) (stating that a plaintiff's failure to warn claim involved matters of fact and accordingly could not be resolved at the motion to dismiss stage); but see Dye v. Covidien LP, 470 F.Supp.3d 1329, 1341 (S.D.Fla. 2020) (stating that Courts in the Eleventh Circuit have rejected prematurity arguments regarding failure to warn claims at the motion to dismiss stage).

Accordingly, the Court will deny Ethicon's Motion as to Count III for strict products liability – failure to warn in its entirety and Counts I and XIV to the extent they allege failure to warn.

3. Manufacturing Defect

Kramer asserts claims for manufacturing defect as part of her negligence claims (Counts I and XIV) and her strict liability – manufacturing defect claim (Count II). (See, e.g., Compl. ¶¶ 95–96, 100–06). Ethicon argues these claims are deficient because Kramer does not allege a specific defect in the manufacturing process in her Complaint. Kramer does not respond substantively, but instead indicates that a ruling on the manufacturing

defect claim is "premature." (Pl.'s Opp'n at 11). At bottom, the Court agrees with Ethicon and will dismiss Kramer's manufacturing defect claims.

To state a claim for manufacturing defect under Maryland law, a plaintiff must allege facts establishing that the product at issue either was not manufactured in accordance with the product's design specifications or that some other error occurred during the manufacturing process. Shreve, 166 F.Supp.2d at 411; see also Phipps v. Gen. Motors Corp., 363 A.2d 955, 959 (Md. 1976) (concluding that a manufacturing defect results when "the defect is a result of an error in the manufacturing process, that is where the product is in a condition not intended by the seller"). Because a manufacturing defect claim focuses on the conduct or procedures involved in the manufacturing process, it is insufficient to simply allege "that the product [was] defective at the time it left the manufacturer's control." Shreve, 166 F.Supp.2d at 411. As with the design defect and failure to warn claims, negligence theory and strict liability manufacturing defect claims require a showing of the same three elements, "defect, attribution of defect to the seller, and a causal relationship between the defect and the injury." Morris, 491 F.Supp.3d at 103.

In Count I of the Complaint, Kramer alleges that Ethicon did not manufacture the mesh products in a manner that would avoid the unreasonable risk of harm to women treated with them. (Compl. ¶ 96). In Count II, she alleges that the products "deviated materially from their design and manufacturing specifications and/or such design and manufacture posed an unreasonable risk of harm." (Id. ¶ 101). Kramer does not, however, identify a specific defect she alleges occurred in the manufacture of the mesh products or precisely how her implant departed from Ethicon's design specifications. By failing to

allege these facts, Kramer has failed to state a claim for manufacturing defect. See Wohlberg v. Ethicon, Inc., No. GLR-20-2093, 2021 WL 1530088, at *2 (D.Md. April 19, 2021) (finding that plaintiff failed to state a claim for manufacturing defect where she failed to "identify any specific defect in the manufacturing process of her Gynecare implant" or "allege how the Gynecare implant departed from Ethicon's intended design specifications for the device"); Figeroa v. Ethicon, Inc., No. 2:19-CV-01188 KWR/KRS, 2020 WL 1434249, at *3 (D.N.M. Mar. 24, 2020) (dismissing manufacturing defect claims due to plaintiff's "fail[ure] to allege that the mesh deviated from Defendants' design specifications"); Kuchenbecker v. Johnson & Johnson, No. 19-61712-CIV, 2019 WL 4416079, at *2 (S.D.Fla. Sept. 16, 2019) ("[T]he Complaint fails to specify how the device implanted in the Plaintiff deviated from manufacturing specifications. Without more, the Court simply cannot draw the reasonable inference that Defendants defectively manufactured the [device] that was implanted in the Plaintiff.").

Accordingly, the Court will dismiss Count II in its entirety and Counts I and XIV to the extent they allege a manufacturing defect.

4. Negligence

Kramer asserts claims for negligence (Count I) and gross negligence (Count XIV) premised on design defect, failure to warn, and manufacturing defect. As explained more fully above, the Court has addressed the three claims under both negligence and strict liability theories and has found that Kramer states a claim for design defect and failure to warn, but not for manufacturing defect. See supra Sections II.B.1–3. Accordingly, the Court will deny Ethicon's Motion as to the negligence counts to the extent Kramer alleges

a design defect or failure to warn and will grant Ethicon's Motion to the extent Kramer alleges a manufacturing defect.

5. Fraud

Kramer asserts claims for common law fraud (Count VI) and fraudulent concealment (Count VII). As she fails to state a claim for fraud under the heightened requirements of Rule 9(b), Counts VI and VII will be dismissed.

The elements of common law fraud are:

> (1) the defendant made a false representation to the plaintiff, (2) the falsity of the representation was either known to the defendant or the representation was made with reckless indifference to its truth, (3) the misrepresentation was made for the purpose of defrauding the plaintiff, (4) the plaintiff relied on the misrepresentation and had the right to rely on it, and (5) the plaintiff suffered compensable injury as a result of the misrepresentation.

Brooks v. Mortg. Inv'rs Corp., No. WDQ-13-1566, 2014 WL 105477, at *5 (D.Md. Jan. 8, 2014) (quoting Hoffman v. Stamper, 867 A.2d 276, 292 (Md. 2005)).

Under Maryland law, the elements of fraudulent concealment are:

> (1) the defendant owed a duty to the plaintiff to disclose a material fact; (2) the defendant failed to disclose that fact; (3) the defendant intended to defraud or deceive the plaintiff; (4) the plaintiff took action in justifiable reliance on the concealment; and (5) the plaintiff suffered damages as a result of the defendant's concealment.

Doll v. Ford Motor Co., 814 F.Supp.2d 526, 537 (D.Md. 2011).

Because both these claims sound in fraud, Kramer must meet the pleading requirements of Rule 9(b). Brooks, 2014 WL 105477, at *4. "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake."

Fed.R.Civ.P. 9(b). In order to meet this heightened pleading standard, a plaintiff "must, at a minimum, describe the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." My Nat'l Tax & Ins. Servs., Inc. v. H&R Block Tax Servs., Inc., 839 F.Supp.2d 816, 818 (D.Md. 2012) (quoting United States ex rel. Wilson v. Kellogg Brown & Root, Inc., 525 F.3d 370, 379 (4th Cir. 2008)). "These facts are often referred to as the 'who, what, when, where, and how' of the alleged fraud." Id. (quoting Wilson, 525 F.3d at 379). A "lack of compliance with Rule 9(b)'s pleading requirements is treated as failure to state a claim under Rule 12(b)(6)." Dunn v. Borta, 369 F.3d 421, 426 (4th Cir. 2004) (quoting Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 783 n.5 (4th Cir. 1999)).

Ethicon argues that Kramer's fraud allegations do not meet the heightened pleading standard set forth in Rule 9(b). Kramer responds by pointing to specific language in her Complaint that she contends is sufficient to meet the standard. The Court agrees with Ethicon.

Kramer identifies the following "particularized" language she contends meet the 9(b) standard:

> 29. The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 2011 Safety Communication.
>
> 30. In fact, at the time Defendants began marketing each of it Pelvic Mesh Products were associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011 Safety Communication.
>
> 35. The Defendants suppressed this information and failed to accurately and completely disseminate or share this and other

> critical information with the FDA, health care providers, and the patients. As a result, the Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the Pelvic Mesh Products and the procedures for implantation were and are safe and effective, leading to the prescription for and implantation of the Pelvic Mesh Products into Plaintiff.

(Compl. ¶¶ 29–30, 35). The allegations set forth above are insufficient to meet the standards of Rule 9(b). First, Kramer does not direct the Court to a specific false statement made by Ethicon. Rather, she offers specifics regarding notifications issued by the FDA, but none issued by Ethicon. Further, throughout the remainder of the Complaint Kramer offers only conclusory, general allegations regarding Ethicon's representations. (See, e.g., id. ¶ 18 (stating that Ethicon "misrepresented the risks" of the products); ¶ 21 (indicating that Ethicon "withheld information"); ¶ 24 (describing Ethicon's "chronic underreporting"); ¶ 34 (stating that Ethicon "suppressed" information and "actively and intentionally misled" the public); ¶¶ 46–47 (describing "representations" made to the medical community without identifying what those representations were)). Without specific information regarding the substance of the alleged misrepresentations, when they occurred, to whom they were made, or how they were disseminated, Kramer's allegations are too generalized to meet the heightened standard of Rule 9(b). See Grinage v. Mylan Pharms., Inc., 840 F.Supp.2d 862, 872 (D.Md. 2011) (finding that plaintiff failed to meet heightened standard of Rule 9(b) for fraud claim where complaint contained no reference to a specific communication constituting misrepresentation); Merino, 536 F.Supp.3d at 1287–88 (finding that plaintiff in pelvic mesh case failed to meet 9(b) standard where she provided

only generalized allegations of fraud and misrepresentation in her complaint); Zetz v. Boston Sci. Corp., 398 F.Supp.3d 700, 713–14 (E.D.Cal. 2019) (same) (citing cases).

For these reasons, Kramer's claims for fraud (Counts VI & VII) will be dismissed.

6. Negligent Misrepresentation

Kramer asserts a claim for negligent misrepresentation (Count IX). Like the fraud claims, because Kramer fails to identify a specific false statement, her reliance on said statement, and harm, the claim will be dismissed.

The elements of negligent misrepresentation in Maryland are:

> (1) the defendant, owing a duty of care to the plaintiff, negligently asserts a false statement;
> (2) the defendant intends that his statement will be acted upon by the plaintiff;
> (3) the defendant has knowledge that the plaintiff will probably rely on the statement, which, if erroneous, will cause loss or injury;
> (4) the plaintiff, justifiably, takes action in reliance on the statement; and
> (5) the plaintiff suffers damage proximately caused by the defendant's negligence.

Rucker v. Branch Banking & Tr. Co., No. GJH-20-0881, 2021 WL 962516, at *9–10 (D.Md. Mar. 14, 2021) (quoting Lloyd v. Gen. Motors Corp., 916 A.2d 257, 273 (Md. 2007)). Accordingly, in order for Kramer to effectively plead negligent misrepresentation, she must allege sufficiently that she justifiably relied on a misrepresentation by Ethicon and suffered a compensable injury as a result. See id. at *10.

As explained more fully above, Kramer fails to identify a specific false statement made by Ethicon. Further, she does not allege that she relied on any specific statement or

that she suffered any injury proximately caused by Ethicon's negligent misrepresentations. As such, Count IX will be dismissed.

III. CONCLUSION

For the foregoing reasons, the Court will grant in part and deny in part Defendants Ethicon, Inc., Ethicon, LLC, and Johnson & Johnson's Motion for Judgment on the Pleadings (ECF No. 18). A separate Order follows.

Entered this 28th day of December, 2021.

/s/
George L. Russell, III
United States District Judge